

Remarks

This Amendment is in response to the Office Action dated **September 5, 2008**.

No claims have been amended.

Claims 20-25, 29-30, 6-7, 9-11, and 13-14 are pending. Claim 20 is independent, the remaining claims depend directly or indirectly from claim 20.

Claim Rejections 35 USC §103

Claims 20-25, 29-30, 6-7, 9-11, and 13-14 have been rejected as obvious from Wang, et al, US 6,465,067 ("Wang") in view of Forte et al US 2003/005161 ("Forte"). The rejection is traversed. Reconsideration is requested.

The rejection clearly fails to establish *prima facie* obviousness of the invention of independent claim 20. At least for this reason the rejection fails as to all of the rejected claims.

When determining obviousness using a combination of references, the prior art must be considered as a whole, without the benefit of the impermissible hindsight vision afforded by the claimed invention. The prior art must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the applicant's invention. Taking into account the evidence of common knowledge and the common sense of the skilled person, there must be some evidence of a suggestion, teaching or motivation that would have led the skilled person to produce the invention as claimed. *In re Translogic Technology Inc.*, 84 USPQ2D 1929, 1937 (Fed. Cir. 2007); *Ortho-Mcneil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2D 1196, 1201-1202 (Fed. Cir. 2008).

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) states: "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational

underpinning to support the legal conclusion of obviousness."

It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. MPEP 2142, discussing the legal concept of *prima facie* obviousness articulates how the obviousness determination is to be made:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

Wang shows variation of composition between different layers of an tubing extrusion for a medical balloon, it does not show or suggest variation between two regions of a single layer of material.

The Office Action contends that Forte "shows that it is known to carry out a method of making *an extruded polymeric article* wherein the crystallization modifier can be present *in any desired distribution or fashion*, depending on the desired article" (emphasis added). This assertion is clearly wrong. The assertion attributes to Forte teachings that are not found or suggested anywhere in the document.

Firstly, as to "an extruded polymeric article," Forte pertains to packaging film that tears easily. It relates neither to extruded polymer articles generally nor to medical devices

particularly. The Office Action fails to articulate a reason why one would combine the Wang et al and Forte documents in fashioning a medical device part. In particular why would one look to techniques for preparing tearable packaging film when forming medical balloons of the type described by Wang? Generally one wants medical balloons to have high tear strengths. Forte's film compositions would not be of interest to a person making a Wang balloon.

Secondly, to support the "any desired distribution or fashion" assertion, the Office Action cites paragraphs 0013, 0014, 0036, 0040, 0041. Those paragraphs are reproduced below in their entirety:

[0013] The film may be a single layer film or a multilayer film. In multilayer embodiment, skin layers with standard homopolymer polypropylene and no hcPP may encapsulate a core layer that includes hcPP and standard homopolymer polypropylene resins. Because the more crystalline core layer is positioned between two less crystalline layers, the film is more easily processed and has increased durability. Another multilayer embodiment has a core layer and two skin layer, each of the three layers containing hcPP resin.

[0014] The amount of hcPP resin contained within each layer may vary according to the properties desired in the film. For example, all layers may contain the same amount of hcPP resin. As a result, the layers have similar or the same viscosities and may be simultaneously co-extruded on standard co-extrusion equipment without the addition of processing acids.

[0036] The inventive film may be a single layer film or multilayer film, extruded by conventional extrusion or coextrusion processes well known in the art. The polymer resins for each layer are melted and mixed with any additives in an extruder. The resins are then extruded (or coextruded in the case of multilayer films) through a slot die.

[0040] In multilayer embodiments the core layer preferably contains greater amounts of hcPP than the skin layers. In some embodiments, one or both of the skin layers may include no highly crystalline polypropylene. An embodiment with at least one hcPP-free skin layer will make the film more durable because it protects the crystalline, easy to tear core layer. Similarly, skin layers with less hcPP than the core provide some protection and added durability.

[0041] Alternatively, the skin layers and core layer may have identical amounts of hcPP. As discussed above, coextrusion of layers with similar or the same viscosities may be simultaneously coextruded on standard coextrusion equipment without the addition of processing agents to increase or decrease viscosity of the resins. Therefore, embodiments

with similar or identical amounts of hcPP may have good processing efficiency.

The description above teaches that, for the disclosed tearable packaging film, in any particular layer of the film the amount of the hcPP resin contained in that layer can be adjusted to suit the desired property of the layer. Further, between different layers of multilayer extruded film, the amount of crystalline hcPP and standard homopolymer polypropylene resins may be the same or different. Nothing in these paragraphs says anything about a crystallization modifier being present "in any desired distribution or fashion." In particular there is nothing that would lead one to vary the composition within a single layer in different regions of that layer.

Review of Forte in its entirety reveals that when compositional variation is described it is either 1) a choice of a particular composition from a range of available compositions, or 2) compositional variation between layers. This is not "any desired distribution or fashion." No reasonable reading of Forte et al would lead a skilled person to conclude that the document teaches or suggests use of crystallization modifier in *every* possible distribution or fashion. The Office Action clearly does not step backward in time as required MPEP 2142. Instead it makes a fictionalized generalization that is not justified by an objective prospective reading of Forte, and does so retrospectively - with reference to the applicant's disclosure. This is impermissible hindsight by definition.

The rejection fails to articulate a reasonable basis for combining the Wang and Forte documents and is founded on an impermissible fictional reconstruction of the Forte teachings. At least for these reasons the claimed invention is not obvious from Wang in view of Forte. Withdrawal of the outstanding rejections is respectfully requested.

Respectfully submitted,
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